UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

FEDERAL TRADE COMMISSION, ***et al.*****,** *Plaintiffs,* v. **GTCR BC HOLDINGS, LLC, *et al.*,** *Defendants*.	Case No. 1:25-cv-02391 Honorable Jeffrey I. Cummings **ANSWER, DEFENSES, AND COUNTERCLAIMS** **PUBLIC VERSION**

ANSWER, DEFENSES, AND COUNTERCLAIMS OF DEFENDANT SURMODICS, INC. TO AMENDED COMPLAINT FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION PURSUANT TO SECTION 13(b) OF THE FEDERAL TRADE COMMISSION ACT

Defendant Surmodics, Inc. ("Surmodics"), by and through its attorneys, hereby admits, denies, avers, and counterclaims as follows with respect to the Amended Complaint filed April 16, 2025, by Plaintiffs the Federal Trade Commission (the "FTC" or "Commission") and the States of Illinois and Minnesota (the "Complaint") in the above-captioned matter relating to the proposed acquisition of Surmodics by GTCR BC Holdings, LLC ("BC Holdings"). To the extent not specifically admitted in the following paragraphs, the allegations in the Complaint are denied. Surmodics states that the introduction, headings, sub-headings, the image labeled "Figure 1," and the Prayer for Relief in the Complaint do not constitute well-pleaded allegations of fact and therefore no response is required. To the extent a response to those matters is deemed required, the allegations are denied. Surmodics reserves the right to amend and/or supplement this Answer.

INTRODUCTION

Surmodics is a manufacturer of lubricious coatings applied to medical devices such as catheters and guidewires. The proposed merger between BC Holdings and Surmodics will lead to enhanced innovation, improved operations, and a redundant supply chain, which will benefit medical device makers who use coatings, clinicians that use coated devices, and patients who receive treatment from procedures involving such devices. In seeking to block the proposed transaction, the Plaintiffs rely on a flawed relevant market analysis which is both too broad and too narrow to accurately capture commercial realities: Too broad because it ignores the significant chemical and use-case differences between the offerings of Surmodics and Biocoat; and too narrow because it improperly excludes from its analysis competitive lubricious coatings from other suppliers, including a significant number of coatings manufactured by large, multi-billion dollar medical device companies.

First, Surmodics's UV-cured hydrophilic coatings and Biocoat's thermal-cured hydrophilic coatings are not close substitutes. While both are lubricious coatings, UV-cured and thermally-cured

hydrophilic coatings are appropriate in different situations and have different chemistries. They involve materially different application processes, too, with UV being generally easier and faster for a medical device maker to implement in its production workflows. The evidence at trial will show there is vanishingly little head-to-head competition between Surmodics's UV-cured hydrophilic coatings and Biocoat's thermally-cured hydrophilic coatings.

After nearly a year of investigative discovery, the FTC has not adduced credible evidence to the contrary. The Complaint mischaracterizes specific customer opportunities and conflates a medical device manufacturer's iterative testing process with actual competition for viable device coatings. Indeed, Surmodics's data and documents illustrate that it competes primarily not with Biocoat's thermally-cured coating, but rather with two other suppliers of UV-cured coatings: Harland and DSM.

Second, Plaintiffs proffer an "outsourced" hydrophilic coatings product market that is too narrow and untethered to the reality of competition for medical device coatings. In particular, Plaintiffs' gerrymandered market ignores that many medical device manufacturers, including some of the largest in the industry, often develop their own lubricious coatings "in-house," and that Surmodics's UV-cured and Biocoat's thermally-cured hydrophilic coatings compete against those in-house coatings. Likewise, Plaintiffs completely ignore other lubricious coatings like hydrophobic and PTFE coatings which can serve as alternatives for hydrophilic coatings.

In sum, the Complaint relies on the construct of a medical device coatings world that is divorced from the technical and commercial realities of the marketplace. Plaintiffs cannot make their prima facie case and, therefore, are not entitled to a preliminary injunction to block this procompetitive transaction.

SPECIFIC RESPONSES TO THE FTC'S ALLEGATIONS

NATURE OF THE CASE

1. GTCR, LLC is a private equity firm based in Chicago, Illinois, which in late 2022 acquired a majority stake in Biocoat, Inc. ("Biocoat"), the second-largest provider of hydrophilic coatings in the United States. GTCR, LLC, through its affiliate, GTCR BC Holdings, LLC, now proposes to acquire Surmodics, the largest provider of hydrophilic coatings in the United States. The Proposed Acquisition, if consummated, would result in a combined company that controls over 50 percent of the market for outsourced hydrophilic coatings, which are critical inputs into lifesaving medical devices. The Proposed Acquisition may therefore lead to a substantial lessening of competition in an already concentrated market, as well as a loss of head-to-head competition, resulting in lower quality and service levels, diminished innovation, and higher prices for hydrophilic coatings sold to U.S. medical device customers.

ANSWER: As to the first sentence, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and it denies them on that basis. As to the second sentence, Surmodics admits only that BC Holdings proposes to acquire it. The remaining allegations in this paragraph purport to state conclusions of law to which no response is required. To the extent a response is required, Surmodics denies the remaining allegations in this paragraph.

2. Hydrophilic coatings are applied to a wide range of interventional medical devices used inside the human body, such as catheters and guidewires, to perform high-stakes neurological, cardiovascular, and peripheral vascular procedures. These medical devices require hydrophilic coatings to reduce friction during use so that the devices function as intended. The coatings allow physicians to maneuver medical devices within the tight confines of the body—for example, within a blood vessel in the brain—without damaging sensitive tissue or vital structures.

ANSWER: As to the first sentence, Surmodics admits that hydrophilic coatings are applied to interventional devices, that catheters and guidewires are types of interventional medical devices, and that neurological, cardiovascular and peripheral vascular procedures are some of the types of procedures where interventional medical devices are used. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

3. Hydrophilic coatings are primarily purchased by original equipment manufacturers ("OEMs") that design, develop, and manufacture medical devices. OEMs range from large, established companies with numerous commercialized devices to smaller startup companies with new and innovative devices in development. Though hydrophilic coatings can be manufactured by an OEM in-house, the vast majority of OEMs opt to purchase hydrophilic coatings produced by specialized third-party manufacturers, such as Surmodics and Biocoat.

ANSWER: As to the first sentence, Surmodics admits that original equipment manufacturers ("OEMs") are among the purchasers of hydrophilic coatings. Surmodics admits the allegations in the second sentence. Surmodics admits that hydrophilic coatings can and are manufactured by certain OEMs in-house, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the third sentence, and it denies them on that basis.

4. The Proposed Acquisition may be analyzed in a relevant market that is no broader than outsourced hydrophilic coatings. Specialized third-party hydrophilic coating providers are a distinct, critical, and growing part of the medical device ecosystem.

ANSWER: Surmodics denies the allegations in this paragraph.

5. Surmodics and Biocoat are the two leading providers in the outsourced hydrophilic coatings market. Surmodics describes itself as the [redacted] Biocoat likewise describes Surmodics as the "#1 player in our space" and the "market leader," while Biocoat's CEO has described Biocoat as the second-largest player in the "outsourced hydrophilic coating market." OEMs also recognize Surmodics and Biocoat as the two most significant players in the market, noting that both companies have longstanding reputations for producing high performance coatings on FDA-approved medical devices.

ANSWER: As to the first sentence, Surmodics admits that it and Biocoat are among the providers of hydrophilic coatings. Surmodics denies the remaining allegations in this paragraph.

6. The Proposed Acquisition is presumptively illegal because it would significantly increase concentration in the already highly concentrated outsourced hydrophilic coatings market. The Proposed Acquisition would result in GTCR controlling more than 50 percent of the outsourced hydrophilic coatings market in the United States, well above the threshold to establish a prima facie case that the Proposed Acquisition is unlawful. Ordinary course documents, witness testimony, and economic analysis further confirm this strong presumption of illegality.

ANSWER: Denied.

7. This increase in market concentration is especially concerning because [redacted]

ANSWER: Surmodics denies the allegations of the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence, and it denies them on that basis.

8. Moreover, the Proposed Acquisition is unlawful because it would eliminate significant head-to-head competition between Biocoat and Surmodics. Biocoat and Surmodics target the same OEM customers and compete aggressively for their business. Biocoat has identified Surmodics as its "largest competitor." Biocoat executives have discusse [redacted] Surmodics likewise views Biocoat as a [redacted] and has sought to win customers from Biocoat, including [redacted] The head of Surmodics' coatings business, upon learning of GTCR's purchase of Biocoat, declared [redacted] This vigorous head-to-head competition has led both Surmodics and Biocoat to offer higher quality coatings and service, better pricing terms, and more innovative products. The Proposed Acquisition is unlawful because it will eliminate this competition and its attendant benefits, harming OEM customers and, ultimately, patients.

ANSWER: Surmodics denies the allegations in the first and second sentences. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences, and it denies them on that basis. The fifth and sixth sentences purport to quote selectively from documents, and Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context. Surmodics denies the allegations of the seventh and eighth sentences.

9. There are no countervailing factors sufficient to offset the likelihood of competitive harm from the Proposed Acquisition. The merging parties cannot demonstrate that new entry in the market would be timely, likely, or sufficient to offset these anticompetitive effects. Nor can they show cognizable, verifiable, or merger-specific efficiencies sufficient to offset the likely and substantial competitive harm from the Proposed Acquisition.

ANSWER: Denied.

JURISDICTION AND VENUE

10. The Proposed Acquisition constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

11. This Court's jurisdiction arises under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and under 28 U.S.C. §§ 1331, 1337, and 1345. This is a civil action arising under Acts of Congress protecting trade and commerce against restraints and monopolies, and is brought by an agency of the United States authorized by an Act of Congress to bring this action.

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

12. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), provides in pertinent part:

> Whenever the Commission has reason to believe
> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
> the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond. . . .

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

13. In conjunction with the FTC, Plaintiff States bring this action for a preliminary injunction under Section 16 of the Clayton Act, 15 U.S.C. § 26, to prevent and restrain GTCR and Surmodics from violating Section 7 of the Clayton Act, 15 U.S.C. § 18, pending the Commission's administrative trial. Plaintiff States have the requisite standing to bring this action because the Proposed Acquisition would cause antitrust injury in each of the markets in their respective states

for outsourced hydrophilic coatings.

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

14. Defendants and each of their relevant operating affiliates and subsidiaries are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

15. Plaintiff FTC maintains and operates a regional business office in Chicago, Illinois. Plaintiff State of Illinois has a main office in Chicago, Illinois.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

16. Defendants are found, reside, and transact business in this State and District, and are subject to personal jurisdiction therein. Defendant GTCR, LLC's principal place of business is Chicago, Illinois, and a substantial portion of the decision making regarding the Proposed Acquisition and the affected commerce described herein has been carried out in this State and District. In formal responses to the Commission's investigation, Defendant GTCR BC Holdings, LLC identified the address of its office or facility as "300 N LaSalle, Suite 5600 Chicago, Illinois 60654," which is also the address of GTCR, LLC.

ANSWER: The first sentence of this paragraph purports to state conclusions of law to which no response is required. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second and third sentences of this paragraph, and it denies them on that basis.

17. The FTC Act, 15 U.S.C. § 53(b), authorizes nationwide service of process, and personal jurisdiction exists where service is effected pursuant to federal statute. Fed. R. Civ. P. 4(k)(1)(C). Venue is proper in the Northern District of Illinois under 28 U.S.C. § 1391(c)(3), as well as under 28 U.S.C. § 1391(c)(2) and 15 U.S.C. § 53(b).

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

THE PARTIES AND THE PROPOSED ACQUISITION

18. Plaintiff FTC is an agency of the United States government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 et seq., with its principal offices at 600 Pennsylvania Avenue, NW, Washington, DC 20580. The FTC is vested with authority and responsibility for enforcing, inter alia, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

19. Plaintiff State of Illinois brings this action by and through its Attorney General. The Attorney General is the chief law enforcement officer for the State and brings this action on behalf of the State and the people of the State of Illinois to protect the State, its general economy, and its residents from the anticompetitive effects of the Proposed Acquisition, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

20. Plaintiff State of Minnesota brings this action by and through its Attorney General. The Attorney General is the chief legal officer for the State and brings this action on behalf of the State and the people of the State of Minnesota to protect the State, its general economy, and its residents from the anticompetitive effects of the Proposed Acquisition, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26

ANSWER: This paragraph purports to state conclusions of law to which no response is required.

21. Defendant GTCR BC Holdings, LLC, is an affiliate of Defendant GTCR, LLC, which is a private equity firm founded in 1980 and headquartered in Chicago, Illinois. At all relevant times, Defendant GTCR, LLC and its executives and affiliates led the decision-making and due diligence regarding the Proposed Acquisition. GTCR owns a portfolio of companies in the medical technology, pharmaceutical, financial services, media, and telecommunications industries. Since 2000, GTCR has invested in approximately 125 portfolio companies and currently manages $40 billion in equity capital.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

22. On November 2, 2022, GTCR announced that it had made a majority investment in Biocoat. GTCR gained a controlling interest in Biocoat, and GTCR and its affiliate, Regatta Medical [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

23. Biocoat, founded in 1991, is a hydrophilic coating provider headquartered in Horsham, Pennsylvania. Biocoat operates two different business segments: coating products and coating services. Biocoat's coating products unit formulates and sells hydrophilic coatings directly to customers under the brand name "Hydak." Biocoat's coating services unit provides two distinct services: (1) application development, which assists medical device companies in optimizing Biocoat's coating chemistry for their products; and (2) commercial coating services, which coats customers' devices with the optimized coating.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

24. Surmodics, founded in 1979 and headquartered in Eden Prairie, Minnesota, is a publicly traded company that sells medical devices, in-vitro diagnostics, and hydrophilic coatings. Like Biocoat, Surmodics offers both hydrophilic coating products and related services, such as application development, regulatory and commercialization support, and commercial coating services. Surmodics' hydrophilic coatings are generally marketed under the brand names "Serene" and "Preside." Surmodics also develops and markets its own interventional medical devices under the brand names "Pounce" and "Sublime."

ANSWER: Surmodics admits the allegations of the first sentence. As to the second sentence, Surmodics admits that it offers hydrophilic coatings and related services to customers. As to the third sentence, Surmodics admits that it markets certain hydrophilic coatings under the brand names Serene™ and Preside™, but it denies that those are the only hydrophilic coatings that it commercializes. As to the fourth sentence, Surmodics admits that it markets certain interventional medical devices under the brand names Pounce™ and Sublime™.

25. Pursuant to a merger agreement dated May 28, 2024, GTCR, through its corporate affiliates and their subsidiaries, agreed to acquire Surmodics for $43 per share, for a total valuation of approximately $627 million.

ANSWER: Admitted.

INDUSTRY BACKGROUND

26. Hydrophilic coatings are applied to interventional medical devices such as catheters, guidewires, sheaths, and stents, that are inserted into confined spaces in the human body. These coated devices are used in a range of interventional procedures such as neurovascular, structural heart, coronary, and peripheral vascular procedures.

ANSWER: Admitted.

27. Although they are a relatively small part of the overall cost of a medical device, hydrophilic coatings are critical to a device's safety and performance. They increase the lubricity of the device, enabling physicians to navigate the device through small, sensitive structures, such as blood vessels, without causing abrasions. Without a hydrophilic coating, excessive friction created by the medical device's movement could damage vital structures within the patient.

ANSWER: Surmodics admits that, to the extent they are applied, hydrophilic coatings are a relatively small portion of the cost of a medical device, and that they increase the lubricity of interventional medical devices. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the first and second sentences in this paragraph, and it denies them on that basis. Surmodics denies the allegations in the third sentence.

28. A hydrophilic coating's performance primarily turns on three criteria:

a. lubricity, a measure of the reduction in friction that occurs when a medical device has a hydrophilic coating;
b. particulate count, which measures the amount of hydrophilic coating particles that are shed from the medical device during use; and
c. durability, which measures the hydrophilic coating's ability to maintain its quality of performance, including its high lubricity and low particulate count, over time.

ANSWER: Surmodics admits that lubricity, particulate count, and durability are among the criteria for assessing a hydrophilic coating's performance. Surmodics denies the remaining allegations in this paragraph.

29. The FDA tests the performance and safety of hydrophilic coatings during its review of the medical devices that use them. An OEM with a medical device that is rejected by the FDA due to poor hydrophilic coating performance can be set back by millions of dollars and multiple years. OEMs typically hedge against that risk by relying on hydrophilic coating providers with a reputation for high performance, good service, and a history of FDA approvals.

ANSWER: Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the second and third sentence in this paragraph, and it denies them on that basis. Surmodics denies the

remaining allegations in this paragraph.

30. Most hydrophilic coatings consist of both a base coat and a top coat. Like paint primer, the base coat is used to normalize and prepare the surface (referred to as the "substrate") of the medical device for coating. Typically, the base coat can better chemically bind to a wider range of substrates (e.g., different polymers, metals, and other surface materials) than the top coat and is itself a superior substrate for the top coat to bind to as well. The top coat is then applied onto the base coat, and it is the top coat which gives the medical device its lubricity.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the first sentence, to the extent it refers to "most" hydrophilic coatings, and it denies them on that basis. Surmodics admits the remaining allegations in this paragraph insofar as they pertain to Surmodics's two-coat hydrophilic coatings. Surmodics states that the image labeled "Figure 1" does not constitute well-pleaded allegations of fact and therefore no response is required. Surmodics denies the remaining allegations in this paragraph.

31. Hydrophilic coatings are typically applied by either dipping the medical device in the coating liquid or by spraying the coating on. After the coating has been applied, it must then be cured. The method for curing will depend on the chemistry of the specific hydrophilic coating. The two most common ways to cure hydrophilic coatings are either by heating them in an oven (thermal curing) or by exposing them to UV light (UV curing).

ANSWER: Admitted.

32. Competitors and OEMs that participate in the outsourced hydrophilic coatings market consistently report that both thermal and UV curing are suitable for the vast majority of medical devices. One hydrophilic coating competitor estimated that [redacted] OEMs typically select a hydrophilic coating supplier based on overall performance and track record of FDA approval rather than the method of curing. For a small subset of devices, however, only one method is suitable: *either* thermal curing *or* UV curing. Thermal curing is generally required, for example, to coat the inner diameter of medical devices, where UV light may not be able to reach, and UV curing may be required for devices that react poorly to very high temperatures.

ANSWER: Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second and third sentence, and it denies them on that basis. Surmodics denies the allegations in the fourth and fifth sentences. To the extent hydrophilic coatings are used,

Surmodics admits that UV-curing may not be suitable to cure the coating on the inner diameter of medical devices, and thermal curing may not be suitable for medical devices that react poorly to high temperatures. The remaining allegations of the fifth sentence of this paragraph are denied.

33. OEMs often engage with hydrophilic coating providers very early in the process of developing a medical device—either a new device or the next generation of an existing product—to determine which hydrophilic coating might best serve their needs. First, the OEM conducts initial testing, also referred to as a feasibility study. As part of the feasibility study, the OEM sends samples and design specifications of their product to the hydrophilic coating provider, which then adjusts its hydrophilic coating formula and process based on the device substrate and the OEM's performance goals. As part of this process, OEMs may test each coating sequentially or conduct feasibility studies with multiple coating providers at the same time before selecting the provider and coating that offers the best mix of performance, service, and price.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

34. The next step in the coating selection process is optimization. Once an OEM has identified its preferred coating formulation, the OEM will continue to work with the coating provider to make further adjustments to the coating's formulation and application process. This iterative process occurs while the OEM continues to adjust the design of the medical device itself, as both the OEM and hydrophilic coating provider strive to achieve an optimal dynamic between the coating and device substrate.

ANSWER: As to the first sentence, Surmodics admits that it works with OEMs to optimize the performance of Surmodics's coatings on the OEMs' devices. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

35. Once a hydrophilic coating is finally "locked in," the coating provider may also offer development and commercialization support, which includes a range of services to help prepare the OEM to launch the medical device. For example, the coating provider may itself apply the coating to the medical devices for pre-clinical or early commercial use. The coating provider may also work with the OEM on technology transfer issues to prepare the OEM to take over the coating application process. If the OEM plans to coat the devices itself, the coating provider will work out an arrangement to supply the proprietary reagents needed to do so. Finally, the coating provider may provide regulatory support to the OEM as it seeks FDA approval for its device. Although the FDA does not require hydrophilic coatings on medical devices, if an OEM submits a device for review with a hydrophilic coating, the FDA will examine the safety and efficacy of

the coating along with the rest of the medical device.

ANSWER: As to the first sentence, Surmodics admits that it offers a range of services to help OEMs prepare to launch their coated medical devices. Surmodics admits the allegations of the second and third sentences. As to the fourth sentence, Surmodics admits that some OEMs purchase coating reagents; otherwise, Surmodics denies the allegations on the grounds that some OEMs manufacture their own coating in-house. Surmodics admits the allegations of the fifth sentence. As to the sixth sentence, Surmodics admits that the FDA, in evaluating for approval a medical device that uses a Surmodics hydrophilic coating, may reference Surmodics's Master File for the hydrophilic coating on the device; otherwise, Surmodics denies the allegations insofar as they suggest Surmodics's coating is subject to "FDA approval."

36. Hydrophilic coating providers derive the vast majority of their revenue from sales of commercialized medical devices. Although hydrophilic coating providers typically do not start earning any revenue related to the sale of a commercialized medical device until two to four years after the beginning of feasibility testing, successful medical devices may be sold on the market with the same hydrophilic coating for over a decade. The coating provider generates some revenue by selling coating reagents to the OEM for the entire lifecycle of the device but typically earns more revenue from a licensing agreement between the coating provider and the OEM for continued use of the proprietary coating, under which the coating provider may receive various licensing fees and milestone payments and, more importantly, an additional payment for each unit of the medical device sold. This additional payment can take the form of a fixed amount per unit sold or a royalty (i.e., a percentage of the average sale price).

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence insofar as they contain generalizations about other hydrophilic coating providers, and it denies them on that basis. As to the second sentence, Surmodics admits that medical devices may be sold on the market with the same hydrophilic coating for over a decade; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence insofar as they contain generalizations about other hydrophilic coating providers.

As to the third sentence, Surmodics admits that it can earn revenue by selling reagents or by executing license agreements that provide for the payment of certain license fees, milestone payments, or royalties; otherwise, Surmodics denies the allegations regarding whether certain payments are "more important[]" than others; Surmodics further responds that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence insofar as they contain generalizations about other hydrophilic coating providers. As to the fourth sentence, Surmodics admits that royalty payments for Surmodics's hydrophilic coatings may be set a fixed rate per unit sold or at a percentage of the average sales price of the medical device; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence insofar as they refer to additional payments to other hydrophilic coating providers.

THE RELEVANT ANTITRUST MARKET, MARKET STRUCTURE, AND THE PROPOSED ACQUISITION'S PRESUMPTIVE ILLEGALITY

37. The Proposed Acquisition would significantly increase concentration in the already highly concentrated market for outsourced hydrophilic coatings in the United States. Surmodics and Biocoat are the top two competitors, and should the Proposed Acquisition be consummated, the merged entity would control over 50 percent of the market. The resulting level of market concentration and the increase in market concentration due to the merger make the Proposed Acquisition presumptively unlawful under the 2023 U.S. Department of Justice and Federal Trade Commission Merger Guidelines (the "Merger Guidelines") and controlling case law.

ANSWER: Denied.

38. The relevant product market is no broader than outsourced hydrophilic coatings. Outsourced hydrophilic coatings have unique characteristics and serve specific customer needs. There are no reasonably interchangeable substitutes for hydrophilic coatings. Although other types of coatings, such as hydrophobic coatings—which repel water rather than attract it—can also provide some lubricity to a medical device, they have a much lower level of performance compared to hydrophilic coatings. Moreover, the most common hydrophobic coating material, polytetrafluoroethylene ("PTFE"), cannot be used to coat the outer diameter of certain medical devices (such as catheters) because PTFE can only be shaped and formed at extremely high temperatures. Coating the outer diameter of a medical device with PTFE at the end of the manufacturing process may damage the rest of the device. Safety and performance concerns related

to the use of PTFE on medical devices have recently led some OEMs to switch from PTFE to hydrophilic coatings, but, for the same reasons, OEMs would not switch from hydrophilic coatings to PTFE, even if prices of hydrophilic coatings increased significantly.

ANSWER: Surmodics denies the allegations of the first and second sentences. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

39. Industry participants—including competitors, customers, and Defendants themselves—all recognize that the outsourced hydrophilic coatings market is a distinct market in which Surmodics and Biocoat are the largest players and frequent head-to-head competitors. Surmodics and Biocoat target many of the same large, small, and startup OEMs for business development.

ANSWER: Denied.

40. Hydrophilic coatings are complicated products that require specialized expertise, years of research, and millions of dollars to develop. As such, small and startup OEMs generally do not have the capabilities to produce their own in-house hydrophilic coatings and must therefore rely on the outsourced market for their coating needs. Moreover, because hydrophilic coatings are a relatively small line item on the total cost of manufacturing a medical device, most larger OEMs also choose not to invest the time or resources into developing an in-house coating.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph insofar as they contain generalizations regarding hydrophilic coatings, OEMs, and the cost of medical devices, and it denies them on that basis.

41. Outsourced hydrophilic coatings from the market leaders, Surmodics and Biocoat, have meaningfully better performance than in-house solutions. They are more lubricious, shed fewer particulates, and have greater durability. Thus, large and small OEMs alike depend on outsourced hydrophilic coatings when their devices have coating performance requirements above and beyond what in-house coatings can offer. Indeed, demand for outsourced hydrophilic coatings is expected to grow as the FDA implements increasingly stringent coating performance requirements, especially with regard to particulate count.

ANSWER: Surmodics denies the allegations of the first and second sentences. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences, and it denies them on that basis.

42. Outsourced hydrophilic coating providers also offer important development and commercialization support and services that many OEMs do not have the expertise, time, or resources to perform themselves. Simply having access to a base hydrophilic coating is insufficient; OEMs depend on feasibility testing and optimization services from hydrophilic coating providers to customize the coating so that it best fits their products. OEMs also depend on the product expertise and technical know-how from hydrophilic coating providers to get their manufacturing started and working smoothly. And OEMs may even depend on outsourced hydrophilic coating providers for contract coating services for their medical devices at all stages of the product's lifecycle, including pre-clinical, clinical, and commercialization.

ANSWER: As to the first sentence, Surmodics admits that it offers a range of services to help OEMs prepare to launch their coated medical devices; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding other hydrophilic coating providers and OEMs, and it denies them on that basis. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

43. For all these reasons, OEMs are unlikely to switch from outsourced hydrophilic coatings to in-house solutions in response to a small but significant price increase.

ANSWER: Denied.

44. The relevant geographic area in which to analyze the effects of the Proposed Acquisition is the United States.

ANSWER: Denied.

45. Hydrophilic coatings are a key component of medical devices. The FDA regulates the production, development, testing, manufacture, marketing, and promotion of medical devices in the United States. A company must perform testing and obtain 510(k) clearance from the FDA, which requires demonstrating substantial equivalence to another legally U.S. marketed medical device, before marketing a medical device in the United States. Accordingly, hydrophilic coatings sold exclusively outside the United States, and not used on devices approved for sale in the United States, are not viable alternatives for U.S. medical device customers, even if the prices for hydrophilic coatings currently available in the United States increase significantly.

ANSWER: As to the first sentence, Surmodics admits that a hydrophilic coating may be a key feature of certain parts of certain medical devices; otherwise, it denies the allegations insofar as medical devices may be uncoated and meet performance

requirements. The second sentence purports to state conclusions of law to which no response is required; to the extent a response is required, admitted. Surmodics denies the allegations of the third sentence.

46. The Proposed Acquisition is presumptively illegal because it significantly increases concentration and results in a highly concentrated market for outsourced hydrophilic coatings. The impact of the Proposed Acquisition on market concentration is sufficient to establish a prima facie case that the Proposed Acquisition violates the antitrust laws.

ANSWER: Denied.

47. The market for outsourced hydrophilic coatings manufacturers is highly concentrated. Surmodics and Biocoat together account for over 50 percent of the outsourced hydrophilic coatings market. The remainder of the market is comprised of smaller hydrophilic coating providers that lack Surmodics' and Biocoat's reputation for high quality coatings and service and track record of coating successful FDA-approved medical devices.

ANSWER: Denied.

48. Surmodics is the acknowledged market leader, generating roughly [redacted] million in annual revenue from its U.S. hydrophilic coatings business in 2023. [redacted] Its customers include large and small OEMs that make devices for neurovascular, peripheral vascular, coronary, and structural heart procedures.

ANSWER: As to the first sentence, Surmodics admits that it believes that in 2023 it generated roughly the alleged amount of revenue in coating services, PreMix services, reagent sales, feasibility fees, license fees, and royalty revenue relating to hydrophilic coatings. As to the second sentence, Surmodics admits only that it enters license agreements with many of its customers that provide for the payment to Surmodics of certain royalties; otherwise, Surmodics denies the allegations of the second sentence of this paragraph insofar as the term "nearly all" is vague. Surmodics admits the allegations in the third sentence.

49. Surmodics' hydrophilic coatings are UV-cured, and its products are sold under the brand names Serene and Preside. Surmodics launched Preside in October 2023 [redacted]

ANSWER: As to the first sentence, Surmodics admits that its hydrophilic

coatings are cured with ultraviolet (UV) light, and that it markets certain hydrophilic coatings under the brand names Serene™ and Preside™; however, Surmodics denies that those are the only hydrophilic coatings that it sells. As to the second sentence, Surmodics admits only that it launched Preside in October 2023; otherwise, Surmodics denies the remaining allegations in the second sentence of this paragraph.

50. Biocoat is the second-largest competitor in the outsourced hydrophilic coatings market and earned approximately [redacted] million in U.S. coatings revenue in 2023. Like Surmodics, Biocoat's revenue is primarily driven by the provision of coatings and coating-related services to OEMs that manufacture neurovascular, coronary, peripheral vascular, and structural heart devices. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

51. Historically, Biocoat specialized in thermal-cured hydrophilic coatings sold under the brand name Hydak. In 2017, Biocoat hired Robert Hergenrother, Surmodics' former Senior Director of Hydrophilic Technologies, as its Senior Director of Research and Development. Under the direction of Dr. Hergenrother, Biocoat developed and launched its own UV-cured hydrophilic coating, called "Hydak UV," in 2020. This development allowed Biocoat to more closely compete with Surmodics for OEMs that had already invested exclusively in UV-curing equipment to apply coatings to their medical devices.

ANSWER: As to the first sentence, Surmodics admits that it understands Biocoat manufactures hydrophilic coatings sold under the brand name Hydak. As to the second, third, and fourth sentences, Surmodics admits that Robert Hergenrother was formerly employed by Surmodics; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Mr. Hergenrother's title, his employment activities at Biocoat, or the effect thereof on Biocoat's ability to compete with other hydrophilic coating providers including Surmodics, and it denies them on that basis. Surmodics denies the remaining allegations of this paragraph.

52. Harland is the third-largest player in the market, generating approximately [redacted] million in coatings-related revenue in 2023. Harland only sells UV-cured hydrophilic coatings, under the brand names Lubricent and Tylicent, which were launched in 2016. Before 2016,

Harland contracted with a smaller hydrophilic coating provider, Innovative Surface Technologies, Inc. (also known as "ISurTec"), to bundle ISurTec's coatings with Harland's equipment.

ANSWER: As to the second sentence, Surmodics admits that it understands Harland sells UV-cured coatings under the brand names Lubricent and Tylicent. Surmodics lacks knowledge or information regarding the remaining allegations in this paragraph, and it denies them on that basis.

53. DSM, which also exclusively sells UV-cured hydrophilic coatings, is the fourth-largest competitor in the market for outsourced hydrophilic coatings, generating approximately [redacted] million in coatings-related revenue in 2023. DSM is a division of dsm-firmenich, a Dutch company focused on health and nutrition.

ANSWER: As to the first sentence, Surmodics admits that DSM sells hydrophilic coatings. Surmodics lacks knowledge or information regarding the remaining allegations in this paragraph, and it denies them on that basis.

54. Several smaller market participants, including Hydromer and ISurTec, collectively comprise the remainder of the outsourced hydrophilic coatings market. These companies do not offer the same level of performance, track record of success, or suite of services as Surmodics and Biocoat.

ANSWER: Denied.

55. Courts, federal and state agencies, and economists commonly employ market shares and a metric known as the Herfindahl-Hirschman Index ("HHI") to measure market concentration. The HHI for a given market is calculated by summing the squares of the individual firms' market shares. A perfectly competitive market has an HHI approaching zero, whereas a market consisting of a single monopolist (i.e., a pure monopoly) has an HHI of 10,000. A market is considered highly concentrated if it has an HHI of more than 1,800.

ANSWER: To the extent the allegations in this paragraph are a legal assertion, no response is required; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

56. An acquisition is presumptively illegal under the Merger Guidelines and controlling case law if it increases the HHI of a relevant market by more than 100 points and either (a) produces a post-acquisition HHI greater than 1,800 points or (b) creates a combined firm with a market share

greater than 30 percent.

ANSWER: To the extent the allegations in this paragraph are a legal assertion, no response is required; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

57. Preliminary information indicates that the outsourced hydrophilic coatings market is already highly concentrated, with an HHI in excess of 1,800. The Proposed Acquisition would result in a merged entity with control of over 50 percent of the relevant market, a post-merger HHI exceeding 3,500 and a change in HHI of over 1,000—levels that substantially surpass the threshold for presumptive illegality. The Proposed Acquisition is therefore presumptively illegal under the Merger Guidelines and controlling case law.

ANSWER: Denied.

58. The Proposed Acquisition is consistent with GTCR's acquisition strategy, dating back to its original Biocoat investment, for an [redacted] in the outsourced hydrophilic coatings market. In a presentation to its investment committee in August 2022, GTCR explained [redacted] and described the outsourced hydrophilic coatings market as having [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

59. To that end, GTCR [redacted] A January 2023 Biocoat board of directors presentation noted tha [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

60. Before pursuing Surmodics, GTCR and Biocoat [redacted] In January 2023, Biocoat's Executive Chairman wrote [redacted] An initial draft of this letter [redacted] in the

medical biomaterials sector, though [redacted] GTCR and Biocoat circled back in January 2024, [redacted] GTCR began exploring an acquisition of the #1 player, Surmodics.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

61. [redacted] On June 3, 2024, after the Proposed Acquisition was announced, GTCR [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

ANTICOMPETITIVE EFFECTS OF THE PROPOSED ACQUISITION

62. Internal documents from both companies, as well as competitor and customer testimony, recognize Surmodics and Biocoat as head-to-head competitors in the outsourced hydrophilic coatings industry. The Proposed Acquisition will eliminate this competition, removing a key driver of quality, competitive pricing, and innovation to the detriment of OEMs and patients that rely on interventional medical devices.

ANSWER: Denied.

63. Surmodics and Biocoat compete head-to-head for customers. The companies target many of the same OEM customers for business development, including both well-established and startup manufacturers.

ANSWER: Denied.

64. Surmodics and Biocoat consistently identify each other as key competitors in the outsourced hydrophilic coatings market. This mutual recognition is evident in numerous internal communications and strategic planning documents from both companies. [redacted] In a July 2022 internal email, [redacted]

ANSWER: As to the first sentence, Surmodics admits that Biocoat is one of many hydrophilic coating providers with which Surmodics competes; Surmodics denies the remaining allegations in the first sentence. The second, third fourth, fifth, and sixth sentences purport to reference documents, and Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

65. Indeed, head-to-head competition between Surmodics and Biocoat accelerated after GTCR acquired Biocoat. For example [redacted] shortly after the Proposed Acquisition was announced [redacted]

ANSWER: Surmodics denies the allegations of the first sentence. The second, third, fourth, fifth, and sixth sentences purport to reference documents, and Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

66. Biocoat similarly views Surmodics as its primary competition. In an email from May 30, 2024, Biocoat's CFO referred to Surmodics as the "#1 player in our space," and Biocoat's CEO identified Surmodics as the "market leader" in a July 2022 email. A May 2024 Biocoat presentation to its board of directors in Chicago describes its position as the "#2 player in the . . . hydrophilic coatings market." Based on Surmodics' stature in the market, Biocoat CEO Jim Moran suggested in a November 2023 email that Biocoat should regularly monitor Surmodics' public financials to "compare [Biocoat's] performance against [its] largest competitor." Mr. Moran also [redacted] In another email from July 2022, Mr. Moran [redacted] And in February 2024, [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

67. Consistent with Defendants' internal communications, customers and competitors of Surmodics and Biocoat describe the two companies as regularly competing head-to-head for new opportunities. OEM customers consistently cite Surmodics and Biocoat as the top two coating providers they considered during medical device development. OEM customers further report that curing method is not a significant factor in choosing a coating provider and that Surmodics and Biocoat compete for their business based on performance, service, and price.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

68. Even for the small share of customers that prefer UV-cured coatings, Surmodics and Biocoat have become increasingly close competitors in recent years. As Biocoat's UV-cured hydrophilic coating, Hydak UV, has gained traction in the market, a significant number of OEMs have benefitted from competition between Hydak UV and Surmodics' hydrophilic coatings. Today, [redacted] Hydak UV, and Biocoat [redacted] Indeed, Biocoat has estimated that Hydak UV [redacted]

ANSWER: Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

69. Surmodics and Biocoat have repeatedly competed head-to-head over the last several years for the same customers and devices, including competition for the following OEMs:

ANSWER: Denied.

a. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

b. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

c. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis. To the extent that the allegations in this paragraph purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

d. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

e. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis. To the extent that the allegations in this paragraph purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

f. [redacted]

[redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis. To the extent that the allegations in this paragraph purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

g. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis. To the extent that the allegations in this paragraph purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

70. Defendants' internal documents show that Surmodics and Biocoat closely monitor each other's business strategy and routinely respond to each other's competitive decision-making. This fierce competition has driven Surmodics and Biocoat to improve coating quality and services, lower prices, and increase innovation. If the Proposed Acquisition is allowed to proceed, current

competition between Surmodics and Biocoat will be eliminated, and the benefits of this competition will likely be lost.

ANSWER: Denied.

71. Current head-to-head competition between Surmodics and Biocoat incentivizes the companies to offer better quality and services than they would absent that competition. Unlike some of their competitors, both Surmodics and Biocoat offer full-service support, including testing, assistance with regulatory approval, and contract coating services, differentiating them from other coating providers. The breadth and quality of their service offerings further differentiates them from other outsourced hydrophilic coating manufacturers in the market.

ANSWER: Denied.

72. For example, when [redacted] became concerned with the performance of Surmodics' hydrophilic coating [redacted] testified that the competition between Surmodics and Biocoat ultimately helped produce a higher quality product offering from Surmodics at better terms.

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

73. [redacted] indicated that Surmodics and Biocoat were the two best options [redacted] and expressed concern that, if the companies merge and the new company reduces choices or services, [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

74. Surmodics and Biocoat compete aggressively on price and pricing structure. [redacted] This price competition benefits customers and drives down costs.

ANSWER: Denied.

[redacted]Price competition can occur in the early stages of development, feasibility testing, optimization, or pre-commercial services. For example, [redacted] Price competition may also occur later in the development process, including in licensing and royalty rates. [redacted]

[redacted]

ANSWER: Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in the second sentence, and it denies them on that basis. Surmodics denies the allegations in the third sentence. To the extent the allegations in the fourth sentence purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context. Surmodics denies the remaining allegations in the fourth sentence of this paragraph.

76. Surmodics and Biocoat also compete on pricing structure. In a presentation to Surmodics' board of directors, Surmodics executives [redacted] Biocoat [redacted] To that end, Biocoat has tried to win business [redacted]

ANSWER: Surmodics denies the allegations in the first sentence. The allegations in the second sentence purport to reference documents, and Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

77. Examples of competition for price and pricing structure between Surmodics and Biocoat include:

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

a. [redacted]

[redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

[redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

c. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

d. [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

78. Surmodics and Biocoat have historically utilized different curing methods for their most popular hydrophilic coatings: Surmodics' Serene coating is UV-cured, while Biocoat's Hydak coating is thermal-cured. More recently, the keen competition between Surmodics and Biocoat has driven both companies to release innovative new products. Biocoat utilized the expertise of Surmodics' former Senior Director of Hydrophilic Technologies, Bob Hergenrother, to develop Hydak UV in 2020. Hydak UV allows Biocoat the opportunity to convert Surmodics customers that are reluctant to use thermal-cured coatings because they have already invested in UV-curing infrastructure. Hydak UV also enables Biocoat to compete for heat-sensitive medical devices that would not withstand thermal curing. Biocoat [redacted]

ANSWER: As to the first sentence, Surmodics admits that its hydrophilic coatings, including the coating that it markets under the brand name Serene, are cured with UV light. As to the second sentence, Surmodics admits that it has innovated and launched two next-generation products since launching Serene. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

79. Surmodics has similarly developed innovative new coatings to better compete with Biocoat. In late 2023, Surmodics released Preside, its next-generation hydrophilic coating, which was developed in part as a response to performance gains made by Biocoat's product offerings in recent years. Surmodics believes that Preside will enable it to more effectively compete with Biocoat [redacted]

ANSWER: As to the first sentence, Surmodics admits that it has launched two next-generation hydrophilic coating products since launching Serene. As to the second sentence, Surmodics admits that it first commercialized its latest-generation hydrophilic coating—marketed under the brand name Preside—in October 2023. As to the third sentence, Surmodics admits that Preside has demonstrated performance improvements compared to Surmodics's legacy hydrophilic coatings, and admits that it competes with many hydrophilic coating providers for OEM customers commercializing medical devices for application in the neurovascular system of the brain. Surmodics denies the remaining allegations in this paragraph.

80. The time and expense Surmodics and Biocoat have invested to develop and market these new and improved coatings demonstrates the ongoing competitive pressure driving innovation in the outsourced hydrophilic coatings market.

ANSWER: Denied.

COUNTERVAILING FACTORS DO NOT OFFSET

THE PROPOSED ACQUISITION'S THREAT TO COMPETITION

81. The Proposed Acquisition raises significant competitive concerns in the outsourced hydrophilic coatings market. Barriers to entry and expansion in the outsourced hydrophilic coatings market are high, and Defendants cannot demonstrate that new entry or expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition.

ANSWER: Denied.

82. As an initial matter, there has not been meaningful new entry into the hydrophilic coatings market in at least five years, and expansion in the industry is slow. [redacted]

ANSWER: Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

83. For a new entrant, the timeline from product development to revenue generation can average between four to seven years. Even for an established player, the development timeline for a new product is at least two years. This is because developing a new hydrophilic coating is a multi-year R&D effort, and once developed and launched, the sales cycle for hydrophilic coatings averages between one to two years and involves multiple rounds of feasibility testing and optimization. In addition, once the OEM has completed feasibility testing and selected a hydrophilic coating for its medical device, it can take at least several more months, if not years, depending on the novelty of the device, for the device to receive FDA approval and begin generating commercial revenue. As such, the average timeline from the launch of a new hydrophilic coating product to the point at which it is ordered on a regular basis for a device is approximately [redacted] years. Biocoat estimates that reaching minimum viable scale could take an average of five to ten years.

ANSWER: Surmodics lacks knowledge or information sufficient to form a

belief as to the truth of the allegations in the first, second, third, fourth, and fifth sentences insofar as they contain vague generalizations regarding product development, and it denies them on that basis. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the sixth sentence, and it denies them on that basis.

84. Two recent examples illustrate the difficulty of launching a new hydrophilic coating product, even for the largest and most sophisticated suppliers. Surmodics began developing its latest generation hydrophilic coating, Preside, [redacted]

ANSWER: Surmodics denies the allegations in the first sentence. As to the second sentence, Surmodics admits that it launched Preside in October 2023; to the extent that this sentence purports to quote documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

85. Likewise, Biocoat [redacted] launch the product in March 2020. Three years later, in March 2023, Biocoat announced that Hydak UV was being used on two FDA-cleared medical devices. Biocoat's May 2024 presentation to its board of directors in Chicago [redacted]

ANSWER: Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

86. The complexity of developing a hydrophilic coating is compounded by the stringent regulatory requirements of the FDA. For medium-risk (Class II) devices, such as catheters and guidewires, the FDA requires a 510(k) Premarket Notification, which involves testing to compare a submitted device to one or more legally marketed medical devices to support a claim of substantial equivalence. Higher-risk (Class III) novel or implantable devices require a Premarket Approval (PMA) application, which involves extensive clinical trials and additional rigorous testing. Critically, both 510(k) and PMA applications must specify the exact hydrophilic coating used in testing. FDA approval is granted for the complete medical device, not individual components, effectively "locking in" the hydrophilic coating for the medical device's lifespan.

ANSWER: The second and third sentences purport to state conclusions of law

to which no response is required; to the extent a response is required, Surmodics admits that medical device manufacturers must obtain 510(k) clearance from the FDA prior to commercializing a device. Surmodics denies the remaining allegations in this paragraph.

87. Changing a hydrophilic coating after a device receives FDA approval requires a new round of development, testing, and FDA application. As a result, OEMs are unlikely to switch to another hydrophilic coating on existing devices unless they are already developing a next-generation version that requires new FDA approval. This "lock-in" effect means that new and existing hydrophilic coatings cannot readily displace existing coatings on commercialized devices.

ANSWER: The first sentence purports to state conclusions of law to which no response is required; to the extent a response is required, Surmodics admits that an OEM that changes the hydrophilic coating for a medical device that has obtained 510(k) clearance from the FDA may be required to obtain a "new" 510(k) clearance from the FDA for the device with the "new" coating; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this sentence, and it denies them on that basis. Surmodics admits the allegations of the second sentence. Surmodics denies the remaining allegations of this paragraph.

88. New coating providers, especially those without existing reputations or relationships, face additional challenges in gaining market traction because OEMs are hesitant to adopt coatings without a proven track record. OEMs prioritize the stability and longevity of their coating providers because they rely on them for extended periods. Many customers are unwilling to be the first to use a new coating that has not previously received FDA approval on another device. Rather, large OEMs typically prefer to partner with full-service coating providers with a proven history of coating FDA-approved devices. Small medical device manufacturers likewise tend to rely on established hydrophilic coating providers because they do not have the resources or time to develop an in-house solution and do not want to jeopardize the launch of the device (and, by extension, the success of the company) by partnering with an unproven coating supplier.

ANSWER: Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

89. Defendants cannot demonstrate merger-specific, verifiable, and cognizable efficiencies sufficient to overcome the structural presumption of illegality or show that the

Proposed Acquisition does not threaten to substantially lessen competition.

ANSWER: Denied.

VIOLATION

COUNT I – ILLEGAL ACQUISITION

90. The allegations of Paragraphs 1 through 89 above are incorporated by reference.

ANSWER: Surmodics incorporates by reference its responses to Paragraphs 1 through 89.

91. The Proposed Acquisition, if fully consummated, may substantially lessen competition in outsourced hydrophilic coatings market throughout the country in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45. Plaintiff States would therefore suffer harm to their general economies and to their residents.

ANSWER: Denied.

LIKELIHOOD OF SUCCESS ON THE MERITS, BALANCE OF EQUITIES, AND NEED FOR RELIEF

92. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the FTC, whenever it has reason to believe that an acquisition is unlawful, to seek preliminary injunctive relief to prevent consummation of the acquisition until the Commission has had an opportunity to adjudicate the acquisition's legality in an administrative trial. Section 16 of the Clayton Act, 15 U.S.C. § 26, authorizes the States of Illinois and Minnesota to sue for and have injunctive relief to prevent threatened loss or damage from Defendants' consummation of the Proposed Acquisition. In deciding whether to grant relief, the Court must balance the likelihood of the Commission's ultimate success on the merits against the public equities. The principal public equity weighing in favor of issuance of preliminary injunctive relief is the public interest in effective enforcement of the antitrust laws. Private equities affecting only Defendants' interest cannot defeat a preliminary injunction.

ANSWER: This paragraph purports to state conclusions of law to which no response is required; to the extent a response is required, Surmodics denies the allegations in this paragraph.

93. The Commission is likely to succeed in proving that the effect of the Proposed Acquisition may be substantially to lessen competition in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, or Section 5 of the FTC Act, 15 U.S.C § 45. In particular, the Commission is likely to succeed in demonstrating, among other things, that:

ANSWER: Denied.

a. The Proposed Acquisition would have anticompetitive effects in the outsourced hydrophilic coatings market;

ANSWER: Denied.

b. Substantial and effective entry or expansion is difficult and would not be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition;

ANSWER: Denied.

c. Any efficiencies and procompetitive benefits asserted by Defendants do not justify the Proposed Acquisition.

ANSWER: Denied.

94. Preliminary relief is warranted and necessary. Should the Commission rule, after the full administrative trial, that the Proposed Acquisition is unlawful, reestablishing the status quo ante if the parties have consummated the Proposed Acquisition and combined their operations in the absence of preliminary relief would be extremely difficult. Moreover, in the absence of relief from this Court, substantial harm to competition would likely occur in the interim.

ANSWER: Denied.

95. Accordingly, the equitable relief requested here is in the public interest. Wherefore, Plaintiffs respectfully request that the Court:

ANSWER: Denied.

a. Enter a temporary restraining order;

ANSWER: The allegations of this sentence do not constitute well-pleaded allegations of fact and therefore no response is required; to the extent a response to those matters is deemed required, Surmodics denies that the Court should grant Plaintiffs' requested relief.

b. Preliminarily enjoin Defendants from taking any further steps to consummate the Proposed Acquisition, or any other acquisition of stock, assets, or other interests of one another, either directly or indirectly;

ANSWER: The allegations of this sentence do not constitute well-pleaded allegations of fact and therefore no response is required; to the extent a response to those

matters is deemed required, Surmodics denies that the Court should grant Plaintiffs' requested relief.

c. Retain jurisdiction and maintain the status quo until the administrative proceeding initiated by the Commission is concluded;

ANSWER: The allegations of this sentence do not constitute well-pleaded allegations of fact and therefore no response is required; to the extent a response to those matters is deemed required, Surmodics denies that the Court should grant Plaintiffs' requested relief.

d. Award costs of this action to the Plaintiff States, including attorneys' fees; and

ANSWER: The allegations of this sentence do not constitute well-pleaded allegations of fact and therefore no response is required; to the extent a response to those matters is deemed required, Surmodics denies that the Court should grant Plaintiffs' requested relief.

e. Award such other and further relief as the Court may determine is appropriate, just, and proper.

ANSWER: The allegations of this sentence do not constitute well-pleaded allegations of fact and therefore no response is required; to the extent a response to those matters is deemed required, Surmodics denies that the Court should grant Plaintiffs' requested relief.

DEFENSES

Without assuming the burden of proof that it would otherwise not bear under applicable law, Surmodics asserts the following defenses:

1. Plaintiffs cannot satisfy their burden of demonstrating an entitlement to a preliminary injunction, which is an extraordinary equitable remedy.

2. Plaintiffs cannot satisfy their burden of demonstrating a likelihood of ultimate success on the merits (*i.e.*, that the proposed transaction is likely to substantially harm competition under Section 7 of the Clayton Act and violate Section 5 of the FTC Act), including because:

a. The Complaint fails to allege a valid product market;

b. The Complaint fails to allege a valid geographic market;

c. The Complaint fails to allege that the proposed transaction will plausibly harm consumers or competition; and

d. The Complaint fails to account for alternative providers of hydrophilic coatings, and it fails to account for new entry and expansion by competitors that is timely, likely, and sufficient.

3. The transaction will result in procompetitive benefits and efficiencies that outweigh any alleged anticompetitive effects.

4. Granting the relief sought is inequitable and contrary to the public interest.

5. The FTC seeks relief through an administrative process that violates Article I of the Constitution, which provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art. I, § 1. Among other things, FTC has total, unguided discretion to decide whether to bring an antitrust enforcement action in an administrative proceeding rather than in an Article III court, in violation of the Non-Delegation Doctrine under Article I.

6. The FTC seeks relief through an administrative process that violates Article II of the Constitution and separation of powers principles because, among other things, the FTC's Commissioners and Administrative Law Judges can only be removed for cause, and for-cause removal restrictions impermissibly restrict the President's removal powers—especially where, as here, an agency exercises substantial executive power. *See* Defs.' Notice of Change in Position at 1, *Express Scripts, Inc. v. FTC*, No. 4:24-cv-1549 (E.D. Mo. Feb. 15, 2025), ECF No. 57.

7. The FTC seeks relief through an administrative process that violates Article III of the Constitution by, for example, adjudicating private rights before a non-Article III body without meaningful review of the FTC's factual findings by an Article III court.

8. The FTC seeks relief through an administrative process that violates Surmodics's right to Equal Protection under the Fifth Amendment. Through a black box "clearance" process, the FTC and the Department of Justice ("DOJ") arbitrarily decide between them which agency will review a transaction. This transaction was reviewed by the FTC, which has the ability to judge the merits of its own case through an in-house proceeding that lacks the protections of an Article III court. By contrast, if the DOJ had reviewed the transaction and decided to challenge it, that challenge could *only* be brought in an Article III court with all the associated protections.

9. The Plaintiffs improperly filed the Amended Complaint without seeking leave of the Court under Fed. R. Civ. P. 21. *Ed Miniat, Inc. v. Globe Life Ins. Group, Inc.*, 805 F.2d 732, 736 (7th Cir. 1986) ("Although Federal Rule of Civil Procedure 15(a) permits a party to freely amend its complaint in a timely fashion, Federal Rule 21 requires a court order to add or drop parties.").

Surmodics furthermore adopts by reference any applicable defense not expressly set forth herein that is pled by BC Holdings in this action. Surmodics has not knowingly or intentionally waived any applicable defenses, and it reserves the right to assert and rely upon any other defenses that may become available or known to Surmodics throughout the course of this action, and to amend, or seek to amend, its answer or defenses.

PRAYER FOR RELIEF

Surmodics respectfully requests that the Court:

A. Dismiss the Complaint with prejudice;

B. Deny Plaintiffs' requested relief;

C. Award to Surmodics the costs incurred in defending this action, including expert's fees and reasonable attorney's fees;

D. Provide any and all further relief as the Court may deem just and proper.

COUNTERCLAIMS

Defendant Surmodics, Inc. ("Surmodics" or "Counterclaim Plaintiff") hereby incorporates, restates, and realleges, as if fully set forth herein, the Counterclaims that Surmodics asserted in the Answer, Defenses, and Counterclaims of Defendant Surmodics, Inc. to Complaint for Temporary Restraining Order and Preliminary Injunction Pursuant to Section 13(b) of the Federal Trade Commission Act, filed March 27, 2025 (ECF No. 48), pursuant to which Surmodics petitioned this Court for declaratory and injunctive relief precluding the Federal Trade Commission ("FTC" or "Counterclaim Defendant") from pursuing an unconstitutional administrative proceeding to prevent BC Holdings from acquiring Surmodics. For the Court's convenience, the allegations from such Counterclaims are restated below in their entirety:

THE PARTIES

1. Counterclaim Plaintiff Surmodics is a publicly owned corporation headquartered in Eden Prairie, Minnesota.

2. Counterclaim Defendant Federal Trade Commission is an agency of the United States government whose principal place of business is Washington, D.C.

JURISDICTION AND VENUE

3. Because this action arises under the Constitution and laws of the United States, this Court has jurisdiction under 28 U.S.C. § 1331.

4. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c)(2), (e)(1) because, on information and belief, Counterclaim Plaintiff BC Holdings resides in this district, and because no real property is involved in this action.

BACKGROUND

A. The FTC's Structure and Administrative Proceedings

5. The Federal Trade Commission Act of 1914 established the FTC as an executive agency led by five Commissioners appointed by the President and confirmed by the Senate. *See* 15 U.S.C. § 41.

6. The FTC is authorized to enforce Section 7 of the Clayton Act, which prohibits mergers that may substantially lessen competition. 15 U.S.C. §§ 18, 21(a).

7. As discussed below, the U.S. Department of Justice is also empowered to enforce Section 7 of the Clayton Act.

8. If the FTC believes that the merger will violate the antitrust laws, the Commissioners may, by majority vote, authorize the FTC to bring a suit challenging the merger.

9. To initiate that suit, the FTC must issue and serve a complaint stating its charges. *See* 15 U.S.C. § 45(b). As a matter of practice, the FTC typically does this by filing an Administrative Complaint in-house with one of its Administrative Law Judges ("ALJ"), who are employed by the FTC, pursuant to the FTC's own administrative rules.

10. If the FTC wants to preliminarily enjoin the merger while the administrative proceedings are ongoing, it must go to federal court and seek a preliminary injunction. 15 U.S.C. § 53(b).

11. Pursuant to the FTC's administrative rules, the ALJ will hold an administrative hearing, which can last up to 210 hours, and will then issue a "recommended decision" as to whether to block the merger. *See* 16 C.F.R. §§ 3.41(b), 3.51(a)(1). Thus, in the FTC's administrative proceedings, FTC employees both draft and resolve the charges brought against the parties to a merger agreement.

12. That "recommended decision" may then be appealed to the Commissioners, the same body that voted to issue the Administrative Complaint in the first place. *See* 16 C.F.R. § 3.54.

13. Unsurprisingly, the FTC is successful when proceeding before itself. The "FTC has not lost a single case in administrative proceedings in the past quarter-century." *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 197, n.1 (2023) (Thomas, J., concurring).

14. The final decision of the Commissioners is subject to very limited judicial review by a U.S. Court of Appeals, 15 U.S.C. § 45(b), where the court is "bound by the Commission's factual determinations so long as they are supported by such relevant evidence as a reasonable mind might accept as adequate. This is so even if suggested alternative conclusions may be equally or even more reasonable and persuasive." *Illumina, Inc. v. FTC*, 88 F.4th 1036, 1046 (5th Cir. 2023).

15. The FTC is also authorized to sue directly in federal court to challenge a merger, rather than go through its own administrative process. 15 U.S.C. § 53(b).

B. <u>The FTC Seeks to Block BC Holdings's Proposed Acquisition of Surmodics</u>

16. In March 2025, the Commissioners voted to authorize the FTC to file an Administrative Complaint in-house seeking an administrative order permanently blocking the merger and, furthermore, requiring prior FTC approval before engaging in a merger with any "other company" for an indefinite "period of time." *See In the Matter of GTCR BC Holdings LLC. et al.*, Dkt. No. 9440 (FTC).

17. At the same time, the FTC filed a suit in this District seeking to preliminarily enjoin the acquisition pending resolution of the administrative proceedings. Compl., *FTC v. GTCR BC Holdings, LLC*, No. 1:25-cv-02391 (N.D. Ill. Mar. 6, 2025), ECF No. 1.

18. The parties have proposed that the preliminary injunction hearing in this Court begin on August 20, 2025. The administrative hearing is set to begin on August 6, 2025. BC Holdings and Surmodics will ask the Commission to continue that hearing until this Court can decide the FTC's

preliminary-injunction request. BC Holdings and Surmodics moved the ALJ to suspend interim deadlines, but that motion was denied on March 27, 2025.

THE FTC'S ADMINISTRATIVE PROCEEDINGS VIOLATE THE CONSTITUTION

A. The FTC Is Violating Article III by Attempting to Adjudicate Surmodics's Private Rights

19. The separation of the legislative, executive, and judicial powers is essential to our system of government. Accordingly, Articles I, II, and III of the Constitution vest the legislative, executive, and judicial powers exclusively in three different branches.

20. The exclusive vesting of the "judicial power" in Article III courts is fundamentally important. Article III has critical protections that guarantee the independence of the courts. Such protections are not present in an in-house FTC proceeding overseen by an FTC employee. For the Framers, ensuring judicial independence was critical.

21. The Constitution thus requires that "judicial power" may only be exercised by Article III judges. Settled law requires that only this "judicial power" may resolve "private rights." This concept is understood to encompass rights belonging to individuals—life, liberty, or property. Generally, unless the substance of a claim has an unbroken historical pedigree of being decided outside traditional courts—like immigration or patents, for example—the case presumptively must be decided by an Article III court. *See SEC v. Jarkesy*, 144 S. Ct. 2117, 2133–34 (2024); *id.* at 2147 (Gorsuch, J., concurring).

22. BC Holdings and Surmodics have entered into a contract by which BC Holdings will acquire Surmodics and all of its properties. The FTC is attempting to void this agreed property transfer through a non-Article III administrative process.

23. Contract and property rights are core private rights subject to suit at common law.

24. Further, common-law courts were charged with deciding competition claims similar to the one the FTC asserts here long *before* the FTC even existed.

25. Similarly, private plaintiffs may pursue similar challenges under the Clayton Act and those suits have long been adjudicated by juries in federal courts.

26. Therefore, the substance of the FTC's claim does not have the required historical pedigree of being decided outside of a court to allow the FTC to sidestep Article III.

27. Because the FTC's administrative proceeding seeks to adjudicate private rights in a non-Article III tribunal, the proceeding violates Article III.

B. The FTC's Purported Ability to Choose Whether to Challenge the Proposed Transaction in an Administrative Proceeding or in an Article III Court Violates the Non-Delegation Doctrine

28. Each branch exercises its constitutionally assigned power exclusively.

29. For that reason, Congress cannot delegate legislative power to an executive agency without an intelligible principle to guide the use of that legislative power.

30. The power to assign disputes to agency adjudication is quintessentially legislative.

31. The FTC Act purports to authorize the FTC to seek permanent injunctive relief against BC Holdings's and Surmodics's proposed transaction either in an Article III court *or* in the FTC's own in-house administrative proceeding.

32. By contrast, DOJ is also empowered to challenge transactions under federal antitrust law, but DOJ must pursue such challenges only before an Article III court.

33. The only guidance provided in the FTC Act is that the FTC should seek permanent injunctive relief from a court in "proper cases." But the meaning of "proper cases" is not clear. The FTC has successfully argued to courts that "proper cases" means nothing more than a case where the FTC has decided to sue in federal court.

34. This "unfettered discretion" to the FTC violates the Non-Delegation Doctrine. *See Jarkesy v. SEC*, 34 F.4th 446, 461–463 (5th Cir. 2022), *aff'd*, 603 U.S. 109 (2024).

C. The FTC's lack of Impartiality and Public Prejudgment of Facts and Law Is Fundamentally Unfair and Violates the Due Process Clause of the Fifth Amendment

35. The FTC has publicly noted their prejudgment of facts and law as to BC Holdings's acquisition of Surmodics. These public statements demonstrate that, having already prejudged the action, the FTC's administrative process violates Surmodics's Fifth Amendment Due Process right to adjudication before a neutral arbiter.

36. After the merger challenge was announced, Chairman Ferguson posted commentary on X.com indicating that he had already formed a view on the merits of the transaction and speculating that it will lead to higher healthcare costs. Additionally, Commissioners Slaughter and Bedoya released an FTC Joint Statement "separately to note that this case is a particularly valuable use of Commission resources because it challenges a transaction that is part of a widespread and problematic playbook in our economy: a private equity giant establishes a position in a market then acquires competing businesses as part of a consolidation strategy." Rebecca Slaughter and Alvaro Bedoya, Statement of Commissioner Rebecca Kelly Slaughter Joined by Commissioner Alvaro M. Bedoya In the Matter of GTCR BC Holdings/SurModics, FTC.gov (March 7, 2025), https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/statement-commissioner-rebecca-kelly-slaughter-joined-commissioner-alvaro-m-bedoya-matter-gtcr-bc. The Commissioners' predetermined opinions, based on facts yet unknown, make it impossible for Surmodics to receive a fair and impartial trial. Such a situation is at odds with our constitution and cannot be allowed to proceed.

D. The FTC's Role as Prosecutor, Judge, and Jury Violates the Due Process Clause of the Fifth Amendment

37. Because the Commission initiated and will adjudicate this action, it violates Surmodics's Due Process right to adjudication before a neutral arbiter. Chairman Ferguson has acknowledged that Congress recognized the role of prosecutor and judge should never reside in the same entity. "Congress sought in the APA to curtail and change the administrative evil[ ] … of embodying in one person or agency the duties of prosecutor and judge." Andrew N. Ferguson, Statement of Commissioner Andrew N. Ferguson Dissenting in Part and Concurring in the Denial of the Motion In the Matter of H&R Block, Inc., et al. Docket Number 9427, FTC.gov, 15 (Oct. 18, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/hrblock-ferguson-statement-dissenting-in-part-and-concurring-in-denial-of-motion.pdf (internal citations omitted). This "administrative evil" will persist so long as the FTC is permitted to both prosecute a case and decide its outcome.

E. The Multilevel Tenure Protections of FTC ALJs and Commissioners Violate Article II

38. Under the FTC Act, FTC ALJs and FTC Commissioners are unconstitutionally insulated from removal by the President and are immunized from accountability to the American voter.

39. As Chairman Ferguson noted, "[d]ual-layer tenure protections for FTC ALJs insulate subordinate officers from the President's control. They undermine self-government and empower the administrative state to the people's detriment." *Id.* at 2.

40. Courts have already found that multilevel tenure protections of ALJs violates the constitution in the context of SEC ALJs. The situation is no different with regards to FTC ALJs. Recognizing the unconstitutionality of multilevel tenure of FTC ALJs, the DOJ stated that the removal restrictions around ALJs are unconstitutional and noted its change of position in *Express*

Scripts, Inc. et al. v. FTC, No. 4:24-cv-1549-MTS, (E.D.M.O. Feb. 15, 2025), stating that: "the Acting Solicitor General has decided that the multiple layers of removal restrictions for administrative law judges in 5 U.S.C. § 7521 do not comport with the separation of powers and Article II and that the Department of Justice will no longer defend them in litigation." Notice of Change in Position 1, ECF No. 57.

41. The same constitutional shortcomings apply to removal protections for FTC Commissioners. The DOJ, the executive branch, and the Chairman of the FTC all recognize this fact. The DOJ has stated that "the Acting Solicitor General has decided that the for-cause removal protections for the Commissioners of the Federal Trade Commission in 15 U.S.C. § 41 likewise do not comport with the separation of powers and Article II and that the Department of Justice will no longer defend them in litigation." *Id.* Consistent with the DOJ's interpretation, the executive branch recently removed two FTC Commissioners and Chairman Ferguson stated that he had "no doubts about [the President's] constitutional authority to remove Commissioners, which is necessary to ensure democratic accountability for our government." Statement of Chairman Andrew N. Ferguson on Former Commissioner Slaughter and Bedoya, FTC.gov, (Mar. 19, 2025), https://www.ftc.gov/news-events/news/press-releases/2025/03/ftc-chairman-andrew-n-ferguson-statement-former-commissioners-slaughter-bedoya.

42. Following the President's recent termination of Commissioners Slaughter and Bedoya, both Commissioners have sued President Trump and the FTC for their reinstatement. *See Slaughter v. Trump*, No. 1:25-cv-00909 (D.D.C. Mar. 27, 2025).

43. In line with the President's efforts, the DOJ's statement, and the statement of the Chairman of the FTC, this Court should likewise recognize that the multilevel removal protection granted to Commissioners under the FTC Act is unconstitutional.

F. Surmodics Is Entitled to Injunctive Relief

44. Surmodics is likely to succeed on the merits. The FTC's administrative proceedings violate constitutional principles. As noted in Section E, the DOJ stated that for-cause removal protections for ALJs and Commissioners do not comport with the constitution and the DOJ will no longer defend ALJs or Commissioners in litigation regarding those protections. Given the DOJ's refusal to defend such actions, Surmodics is likely to succeed on the merits of this challenge.

45. Surmodics is currently being required to undergo an unconstitutional administrative proceeding. This is a "here-and-now injury" that constitutes irreparable harm. *See Axon*, 598 U.S. at 191. That injury is both ongoing and set to escalate with the beginning of the administrative hearing.

46. The FTC will face no hardship by being required to pursue their merger case in federal court. Indeed, they are already pursuing a preliminary injunction in federal court. And DOJ, which is tasked with enforcing the very same law, must always go to federal court to challenge a merger. By contrast, without an injunction, Surmodics will continue to undergo an irreparable hardship of being required to submit to an unconstitutional proceeding that seeks to restrict its contract and property rights. The FTC has recognized that the preliminary injunction proceeding is typically dispositive. *FTC v. Tempur Sealy Int'l, Inc.*, No. 4:24-cv-2508, 2025 WL 617735, at *53 (S.D. Tex. Jan. 31, 2025) ("[T]he parties jointly recognize that the decision as to the preliminary injunction is—at least in the majority of circumstances—determinative of whether the acquisition will ever close.").

47. The public interest favors requiring government agencies to obey the Constitution. And it will not be harmed by requiring the FTC to follow the same process DOJ follows in enforcing the very same law.

COUNT I

(The Administrative Proceeding Violates Article III)

48. Surmodics incorporates by reference and realleges each and every allegation contained

above, as though fully set forth herein.

49. Article III of the U.S. Constitution vests the judicial power of the United States in Article III courts. At a minimum, cases involving private rights may not be heard in tribunals other than Article III courts.

50. The FTC proceeding seeks to adjudicate core private rights, including Surmodics's contract and property rights.

51. Because the proceeding is conducted by an administrative agency, not by an Article III court, the proceeding violates Article III.

52. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding.

53. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

COUNT II

(The FTC's Ability to Proceed Either in an Administrative Proceeding or in Court Violates the Non-Delegation Doctrine)

54. Surmodics incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

55. Congress purported to give the FTC the choice to seek to permanently block a merger either through its own administrative proceedings or in federal court.

56. This is a legislative choice for which Congress failed to provide an intelligible principle.

57. This violates the Non-Delegation Doctrine.

58. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding and require the FTC to seek any relief in court.

59. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

COUNT III

(The Commission's Lack of Impartiality and Public Prejudgment Violates the Due Process Clause of the Fifth Amendment)

60. Surmodics incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

61. The Commission's predetermination of facts and law violates the Due Process clause of the Fifth Amendment.

62. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding.

63. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

COUNT IV

(The FTC's Role as Prosecutor, Judge, and Jury Violates the Due Process Clause of the Fifth Amendment)

64. Surmodics incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

65. The FTC determines which cases to bring in administrative proceedings, prosecutes those cases, and adjudicates the outcome of those cases.

66. This Violates the Due Process Clause.

67. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding.

68. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act,

28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

COUNT V

(Multilevel Tenure Protections of FTC ALJs and Commissioners Violate Article II)

69. Surmodics incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

70. The FTC Act purports to provide multilevel tenure protections for FTC Commissioners and ALJs.

71. These protections violate the President's removal power under Article II.

72. The remedy for this constitutional violation is to enjoin the unconstitutional administrative proceeding.

73. This Court may grant the relief sought under the U.S. Constitution, the All Writs Act, 28 U.S.C. § 1651(a), and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)–2202.

NOTICE OF CONTEMPLATED RELIEF

WHEREFORE, Surmodics respectfully requests that the Court enter and order judgment in its favor and against Counterclaim Defendant:

A. Preliminarily and permanently enjoining the administrative proceeding against BC Holdings and Surmodics; and

B. Declaring that the administrative proceeding against BC Holdings and Surmodics violates Articles II and III and the Fifth Amendment of the U.S. Constitution.

Dated: April 30, 2025

/s/ Paul H. Saint-Antoine

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CERTIFICATE OF SERVICE

I hereby certify that on April 30, 2025, I electronically filed a true and correct copy of the foregoing document using the Court's CM/ECF System, which will send a notice of electronic filing to all counsel of record.

/s Matthew Lechner
Matthew Lechner